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PATENT

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Washington, D.C. 20231

By: 

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Cheever *et al.*

Application No.: Not yet assigned

Filed: March 9, 2001

For: HER-2/NEU FUSION PROTEINS

Examiner: Not yet assigned

Art Unit: Not yet assigned

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Please amend the application as follows:

IN THE CLAIMS

Please cancel claims 1-92 without prejudice to subsequent revival.

Please add new claims 93-112 as follows.

93. An isolated protein comprising a HER-2/neu extracellular domain fused to a HER-2/neu phosphorylation domain, wherein the protein has a sequence at least 80% identical to the sequence of SEQ ID NO:6, or wherein the protein comprises a sequence at least 80% identical to the sequence of SEQ ID NO:3 fused to a sequence at least 80% identical to the sequence of SEQ ID NO:4, and wherein the protein is capable of producing an immune response in a warm-blooded animal.

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94. The protein of claim 93, wherein the protein comprises a sequence at least 80 % identical to the sequence of SEQ ID NO:3 fused to an amino acid sequence at least 80% identical to the sequence inclusive of Gln 991 to Val 1256 of SEQ ID NO:2.

95. The protein of claim 93, wherein the protein comprises a sequence at least 80% identical to the sequence of SEQ ID NO:8 fused to a sequence at least 80% identical to the sequence of SEQ ID NO:4.

96. The protein of claim 93, wherein the protein comprises a sequence at least 80% identical to the sequence of SEQ ID NO:8 fused to the amino acid sequence inclusive of Gln 991 to Val 1256 of SEQ ID NO:2.

97. The protein of claim 93, wherein the HER-2/neu extracellular domain is fused to the HER-2/neu phosphorylation domain via a chemical linker.

98. The protein of claim 97, wherein the chemical linker is an amino acid linker

99. A pharmaceutical composition comprising the protein molecule of claim 93, and a pharmaceutically acceptable carrier or diluent.

100. The pharmaceutical composition of claim 99, further comprising an immunostimulatory substance.

101. The pharmaceutical composition of claim 99, wherein the protein is presented in an oil-in-water emulsion.

102. The pharmaceutical composition of claim 99, wherein the immunostimulatory substance is SBAS2, 3D-MPL, QS21, or a combination of 3D-MPL and QS21.

103. An protein comprising a HER-2/neu extracellular domain fused to a fragment of the HER-2/neu phosphorylation domain, wherein the protein has a sequence at least 80% identical to the sequence of SEQ ID NO:7, or wherein the protein comprises a sequence at least 80% identical to the sequence of SEQ ID NO:3 fused to a sequence at least 80% identical to the sequence of SEQ ID NO:5, and wherein the protein is capable of producing an immune response in a warm-blooded animal.

104. The protein of claim 103, wherein the protein comprises a sequence at least 80% identical to the sequence of SEQ ID NO:3 fused to a sequence at least 80% identical to the amino acid sequence inclusive of Gln 991 to Arg 1049 of SEQ ID NO:2.

105. The protein of claim 103, wherein the protein comprises a sequence at least 80% identical to the sequence of SEQ ID NO:8 fused to a sequence at least 80% identical to the sequence of SEQ ID NO:5.

106. The protein of claim 103, wherein the protein comprises a sequence at least 80% identical to the sequence of SEQ ID NO:8 fused to a sequence at least 80% identical to the amino acid sequence inclusive of Gln 991 to Arg 1049 of SEQ ID NO:2.

107. The protein of claim 103, wherein the HER-2/neu extracellular domain is fused to the HER-2/neu phosphorylation domain via a chemical linker.

108. The protein of claim 103, wherein the chemical linker is an amino acid linker

109. A pharmaceutical composition comprising the protein molecule of claim 103, and a pharmaceutically acceptable carrier or diluent.

110. The pharmaceutical composition of claim 109, further comprising an immunostimulatory substance.

111. The pharmaceutical composition of claim 109, wherein the protein is presented in an oil-in-water emulsion.

112. The pharmaceutical composition of claim 109, wherein the immunostimulatory substance is SBAS2, 3D-MPL, QS21, or a combination of 3D-MPL and QS21.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Annette S. Parent
Reg. No. 42,058

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
SF 1222325 v1